MAY - 3 2001

K010487

VI. Safety and Effectiveness Summary

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87

Establishment Registration Number: 2021898

Address of Manufacturer: Medtronic PS Medical
125 Cremona Drive
Goleta CA, 93117
(805) 968-1546 ext. 1776
Fax: (805) 968-5617

Contact Person: Janet McAuley

Date: February 6, 2001

Trade or Proprietary Name: Medtronic PS Medical BiPolar Pencil

Common usual or Classification Name: Electrosurgical cutting and coagulation device and accessories (878.4400)

Predicate Device Identification: Kirwan BiPolar Pencil (K962678)

Description: The Medtronic PS Medical BiPolar Pencil is used to coagulate vascular tissue (bleeding vessels) to seal openings and control bleeding, and/or to shrink and dissect tissue.

Intended Use: The Medtronic BiPolar Pencil is intended to be used with the Channel Scope Endoscope. It is used to coagulate vascular tissue (bleeding vessels) to seal openings and control bleeding, and/or to shrink and dissect tissue.

Intended Use of predicate device: Kirwan BiPolar Pencil coagulator is designed either as a disposable or reusable product. The bipolar pencil coagulator is an electrosurgical device designed to be used in soft tissue surgical procedures that require low energy output for coagulation of the tissue.

Technological comparison: Medtronic PS Medical submits that the materials of fabrication, intended uses, performance characteristics and design specifications of the BiPolar Pencil are substantially equivalent to those of the predicate device. Based upon the summary above, Medtronic PS Medical determines substantial equivalence, safety, and efficacy of the BiPolar Pencil based upon the predicate and currently marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2001

Ms. Janet McAuley
Regulatory Affairs
Medtronic PS Medical
125 Cremona Drive
Goleta, California 93117

Re: K010487
Trade/Device Name: Medtronic PS Medical BiPolar Pencil
Regulation Number: 878.4400
Regulatory Class: II
Product Code: GEI
Dated: February 15, 2001
Received: February 20, 2001

Dear Ms. McAuley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: BiPolar Pencil

Abbreviated 510(k) Number (if known): K010487

Indications for Use:

The BiPolar Pencil is designed to provide bipolar hemostasis coagulation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Over the Counter Use:
or
Prescription Use:
(Per 21 CFR 801.109)

(optional format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010487